

Secretary for Health and Family Services Final PDL Selections from Pharmacy and Therapeutics Advisory Committee

August 5, 2004 Meeting

This chart provides a summary of final PDL selections that were made by the Secretary for Health and Family Services as a result of the Pharmacy and Therapeutics Advisory Committee meeting of August 5, 2004 resulting in recommendations and product supplemental rebate submissions.

	Description of Recommendation	P & T Vote
#1	<p>Antiemetics, 5HT₃</p> <ol style="list-style-type: none"> All products in the 5-HT₃ class are considered clinically equivalent in efficacy and safety. Select all products as preferred based on economic evaluation. Quantity limits - Place quantity limits on the 5-HT₃ antagonists and on Emend with the quantity limits based on the average quantity per treatment session (and "X" number of sessions per month), and on available package size of each product. Requests for higher doses would require PA. The following are suggested quantity limits based on four cancer treatment cycles per month and adjusted for available package sizes. <ul style="list-style-type: none"> <u>Zofran</u> : 4mg and 8mg: 9 tablets per month 24mg: 3 tablets per month Liquid: 60ml/month Injection: 3 vials 20ml (40mg); and 6 vials 2ml (4mg) <u>Kytril</u>: 1mg tablets: 6 tablets per month Liquid: 80ml/month Injection: 6 vials 1mg/1ml <u>Anzemet</u>: 50mg and 100mg tablets: 5 tablets per month Injection: 3 vials 100mg/5ml; and 6 ampules 12.5mg/0.625ml <u>Emend</u>: 3 Tri-packs (9 tablets) per month PA required. Approval based on stated chemo agent and/or type of radiation. Quantities restricted to those mentioned in guidelines above and number of requested cancer treatments per month. Non-oncology use will be approved on an individual basis based on prior use of first-line antiemetics. For any new chemical entity in the Antiemetic 5-HT₃ class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 	<p>Passed 9 - For 0 - Against</p> <p>-----</p> <p>Recommendations approved.</p> <p>PDL Selections: Zofran, Kytril, Anzemet, Emend, Aloxi</p>
#2	<p>Ophthalmic Antibiotics</p> <ol style="list-style-type: none"> All of the ophthalmic products within each class are considered clinically equivalent in efficacy and safety to the other products in that class, ie; <ol style="list-style-type: none"> Combination Antibiotic Products, Miscellaneous Single Entity Antibiotic Products, Corticosteroid/Antibiotic Combination Products, Fluoroquinolones, 2nd and 3rd generation (Ofloxacin, Ciprofloxacin, Levofloxacin), Fluoroquinolones 4th generation (Gatifloxacin, Moxifloxacin) and Aminoglycosides. Select at least one (1) product from each of the following classes as preferred based on economic evaluation: a). Combination Antibiotic Products b). Miscellaneous Single Entity Antibiotic Products c). Corticosteroid/Antibiotic Combination Products d). Aminoglycosides. Select Ocuflax as preferred for the 2nd and 3rd generation Fluoroquinolone class. Select Vigamox as preferred for the 4th generation Fluoroquinolone class. Consider no more than 3 fills for any ophthalmic corticosteroid/antibiotic combination product during a six month period. For any new chemical entity in the Ophthalmic Antibiotic class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 	<p>Passed 9 - For 0 - Against</p> <p>-----</p> <p>Recommendations approved.</p> <p>PDL Selections: a). Combination Antibiotic Products: Neosporin Oph. Ointment, Polytrim Oph Soln; b). Miscellaneous Single Entity Antibiotic Products: AK-Tracin oint, Bleph-10 soln; c). Corticosteroid /Antibiotic Combination Products:</p>

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		Neo-Decadron Soln, Dexacine oint; d). Aminoglycosides: Garamycin soln. Fluoroquinolones Ocuflox Vigamox
#3	<p>SSRI Antidepressants</p> <ol style="list-style-type: none"> 1. All SSRIs and all dosage forms are clinically equivalent in both efficacy and safety. 2. Place quantity limits of 30 units/30 days, except for generic fluoxetine, for each SSRI. 3. Select at least two (2) branded SSRIs, excluding Paxil CR, Sarafem, Prozac Weekly, to use as preferred agents based on economic evaluation, in addition to generic fluoxetine and paroxetine. 4. Implement a grandfather clause, which allows patients currently on medications not selected as first-line to continue to receive their medication. 5. For any new chemical entity in the SSRI class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 	<p>Passed 9 – For 0 – Against -----</p> <p>Recommendations approved with exception of quantity limits. Quantity limits and PA will be put in place as recommended for those agents that are not subject to tablet splitting restrictions and Lexapro 5mg will have PA with quantity limits of #30/month to encourage splitting of the 10mg dose.</p> <p>PDL Selections: Fluoxetine (with previously approved restrictions) Paroxetine Pexeva Lexapro, with previously approved restrictions with regard to tablet-splitting.</p>
#4	<p>Osteoporosis Agents</p> <ol style="list-style-type: none"> 1. All products in each group are considered clinically equivalent in efficacy: <ul style="list-style-type: none"> • Hormone replacement • SERMs • Bisphosphonates • Calcitonin 2. Select in each group: <ul style="list-style-type: none"> • Hormone replacement -- at least one (1) product to use as preferred based on economic evaluation. • SERMs - at least one (1) product to use as preferred based on economic evaluation. • Bisphosphonates -- at least one (1) product to use as preferred based on economic evaluation. • Calcitonin- at least one (1) product to use as preferred based on economic 	<p>Passed 9 – For 0 – Against -----</p> <p>Recommendations approved.</p> <p>PDL Selections: Hormone Replacement: Premarin, Provera, Prempro, Premphase</p> <p>SERM's:</p>

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	<p>evaluation.</p> <ol style="list-style-type: none"> Place quantity limits of 30 units/30 days for daily dosing regimens. For any new chemical entity in the Osteoporosis Agents class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 	<p>Evista</p> <p>Biphosphonates: Actonel</p> <p>Calcitonin: Miacalcin Nasal Spray</p>
#5	<p>Stimulants, Drugs for ADHD</p> <ol style="list-style-type: none"> All dosages and forms of stimulants (long and short acting) are clinically equivalent in efficacy and safety. All immediate release generic products will be available with out prior authorization. Focalin is PA required (failure of IR generic stimulants first). All extended release stimulant agents are equivalent efficacy and safety. Select at least one methylphenidate extended release product (Ritalin LA, Concerta or Metadate CD) and at least one amphetamine mixed salts product that will be preferred based on economic evaluation. Place a Prior Authorization on Strattera. Continue current quantity limits on Strattera. For all controlled stimulant agents, recommend continue Prior Authorization for any patient > 18 years old. For all stimulant agents, allow only one prescription per month unless switching agents due to therapeutic failure. Grandfather any patient who in the past 3 months has been stabilized on any ADHD treatment protocol. For any new chemical entity in the Stimulant class require a PA and quantity limit until reviewed by the P&T advisory Committee. 	<p>Passed 9 – For 0 – Against</p> <p>-----</p> <p>Recommendations approved.</p> <p>PDL Selections: IR generic products: methylphenidate, dextroamphetamine Methylphenidate</p> <p>Extended release: Metadate CD</p> <p>Amphetamine Mixed Salt: Adderal, Adderal XR</p>
#6	<p>Cephalosporins</p> <ol style="list-style-type: none"> All cephalosporins in each generation are equivalent in safety and efficacy. Select the following as preferred agents based on economic evaluation for each generation: generic cephalixin, Lorabid, generic cefaclor, Suprax, Spectracef, Cefzil and Omnicef. For any new chemical entity in the cephalosporin class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 8 – For 1 – Against</p> <p>-----</p> <p>Recommendations approved.</p> <p>PDL Selections: generic cephalixin, Lorabid, generic cefaclor, Suprax, Spectracef, Cefzil and Omnicef.</p>
#7	<p>Macrolides/Ketolides</p> <ol style="list-style-type: none"> All macrolides are equivalent in safety and efficacy. Select the following as preferred agents, in addition to generic erythromycin, based on economic evaluation: Zithromax, Biaxin, Biaxin XL. Place a prior authorization on Ketek and Dynabac. For all branded agents, recommend quantity limits. 	<p>Passed 9- For 0 -Against</p> <p>-----</p> <p>Recommendations approved with</p>

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	<ul style="list-style-type: none"> - Zithromax 100mg/5ml suspension: 150ml per 30 days. - Zithromax 1 gm packet: #4 per 30days. - Zithromax 200mg/5ml suspension: 75ml per 30days. - Zithromax 250mg tablets: #12 per 30 days. - Zithromax 600mg tablets: #10 per 30days. - Biaxin XL #28 per 30 days - Ketek #20 per 30 days <p>5 For any new chemical entity in the macrolide class, require a PA and Quantity limit until reviewed by the P&T Advisory Committee.</p>	<p>exception of Ketek.</p> <p>PDL Selections: Zithromax, Biaxin, Biaxin XL, Ketek added</p>
#8	<p>Non-Antibiotic Ophthalmic Agents</p> <ol style="list-style-type: none"> 1. All subgroups of drugs listed in each of the 4 main ophthalmic groups, Glaucoma, Allergic Conjunctivitis, Dry Eye Syndrome and Miscellaneous are equivalent in safety and efficacy. 2. Select at least one (1) branded ophthalmic drug from the following classes as preferred agents based on economic evaluation: a). Allergic Conjunctivitis, b). Dry Eye Syndrome, and c). Miscellaneous. 3. Place all ophthalmic drugs used for the treatment of Glaucoma on the preferred drug list. 4. For all branded ophthalmic antihistamine agents, recommend quantity limits. <ul style="list-style-type: none"> - Optivar (azelastine): 6ml per 28 days. - Zaditor (ketotifen): 5ml per 23 days. - Livostin (levocabastine): 10ml per 23 days. - Patanol (olopatadine): 5ml per 23 days. - Elestat (epinastine): 5ml per 23 days. - Emadine (emedastine): 10ml (2 vials) per 23 days. 5. For any new chemical entity in the ophthalmic non-antibiotic class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 	<p>Passed 9- For 0-Against</p> <p>-----</p> <p>Recommendations approved.</p> <p>PDL Selections: a). Allergic Conjunctivitis: Zaditor, generic cromolyn sodium, HMS, Acular</p> <p>b). Dry Eye Syndrome: Refresh, Refresh PM</p> <p>c). Miscellaneous: Opticaine</p> <p>d). Glaucoma - All agents reviewed.</p>